

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 April 2008 has been entered.
2. Claims 1, 4-8 and 17-31 are pending.
3. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims and to the arguments.

Election/Restrictions

4. Newly submitted claims 22-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Newly submitted claim 22 requires a step of preparing a detection instrument which was not required in the method of claim 17, therefore, these claims would require additional search and consideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claims 22-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4-8 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al (US 5,141,850) in view of Fitzpatrick et al (US 5,451,504) and Durst et al (US 5,789,154).

Cole discloses a device and method comprising a water-dispersible labeled component that comprises the coupling product of a first immunologically reaction substance and a detectable species; providing a water-dispersible capturable component that comprises the coupling product of a capturable species and a second immunologically reactive substance; providing a capturable component that is localized at a detection zone in a porous carrier material and which comprises a capturing substance capable of interaction with a reaction product containing the capturable species to thereby capture and collect the product at the detection zone. See column 2, lines 24-62. Cole discloses that the labeled component is initially a dry, reconstitutable,

water-dispersible and diffusible and is reconstituted by the sample liquid. See column 2, line 63 through column 3, line 2.

Cole differs from the instant invention in failing to teach a zone to capture unbound label products. Cole also fails to teach the detection of pollutants such as PCB or dioxins.

Fitzpatrick, however, discloses a device similar to those of Cole. Fitzpatrick further teaches the capture of unbound labeled reagents. See column 1, line 57-68.

And Durst teaches that small analytes such as dioxin and PCBs are easily measurable using conventional techniques. See claim 13.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Cole to include a trap zone to capture unbound labeled reagents such as taught by Fitzpatrick because such modification would provide the advantage of a device that yields a detectable results in the case of a negative test leading to more accuracy in assay interpretation.

A skilled artisan would have had a reasonable expectation of success in assembling the device of Cole as modified by Fitzpatrick in a detection set, i.e. kit, such as taught by Cole because kits provide the advantages of economy and convenience and are well-known in the art.

It also would have been obvious to one of ordinary skill the art at the time the invention was made to use the device of Cole as modified by Fitzpatrick to measure analytes such those taught by Durst because Cole teaches that their device is

appropriate for the detection of a wide variety of analytes with the appropriate selection of reagents.

7. Claims 1, 4-8 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al (US 5,141,850) in view of Fitzpatrick et al (US 5,451,504) and Neuman (US 5,057,275).

See the discussion of Cole and Fitzpatrick above. These references differ from the instant claims in failing to specifically teach reagents for dioxin or PCBs.

Neuman teaches that environmental contaminants such as dioxins and PCBs are easily detected using antibodies specific therefor.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Cole as modified by Fitzpatrick to measure analytes such as those taught by Newman because Cole teaches that their device is appropriate for the detection of a wide variety of analytes with the appropriate selection of reagents.

Response to Arguments

8. Applicant's arguments, filed 30 April 2008, with respect to the rejection(s) of claim(s) 1 under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Applicant's arguments filed 30 April 2008, with respect to the rejections of the claims under 35 USC 103 have been fully considered but they are not persuasive.

Applicant argues that the analysis system of Durst is completely different from the instant claims and does not suggest that dioxin and PCB can be detected with antibodies.

These arguments have been fully considered but are not persuasive. The Durst reference is relied upon for their teaching that analytes such as dioxin and PCBs can be detected using antibodies and that such detection is well known in the art. The device is taught by Cole as modified by Fitzpatrick. The argument that Durst does not teach antibodies specific for dioxin and PCB is not persuasive. Durst teaches binding materials comprising polyclonal or monoclonal antibodies. Binding material can also be any naturally occurring or synthetic receptors that specifically bind the analyte of interest. And receptors are defined as avidin, biotin, thyroxine binding globulin, antibodies, Fab fragments, lectins, etc. See column 8, lines 1-13. And finally, Durst teaches that these binding materials are specific for analytes such as dioxin and PCBs. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in using the device of Cole as modified by Fitzpatrick to detect analytes such as dioxin or PCB as taught by Durst because reagents for these analytes are widely available and their detection is routine in the art.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
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